JUL 2 9 2002

510(k) SUMMARY

510(k) number: K022174

This summary of information is being provided for the modified Aegis Catheter in accordance with 21 CFR 807.92(a).

Applicant Information:	Cardeon Corporation 10161 Bubb Road Cupertino, CA 95014
Contact Person:	Jane Beggs Regulatory Affairs Cardeon Corporation
Date:	15 July 2002
Device Trade Name:	Cardeon® Aegis™ Catheter
Device Common Name	Catheter, cannula and tubing, vascular, cardiopulmonary
Regulation No.:	bypass 870.4210
Classification / Code:	Class II / DWF

Indications for Use: The Cardeon® Aegis™ Catheter is intended to perfuse the aorta during open chest (sternotomy) procedures on cardiopulmonary bypass up to 6 hours.

Summary of Substantial Equivalence: The modified Aegis Catheter is substantially equivalent to the original Aegis Catheter and currently marketed devices with regard to intended use/indications, device performance and technological characteristics. These devices are used to directly cannulate the aorta and return perfusion to patients undergoing general cardiac surgery through standard connections to the extracorporeal circuit. Substantial equivalence is supported through comparison with several marketed devices with the same indications for use, including arterial return cannulae with directed flow (specified flow pattern). Differences between the Aegis Catheter and other devices do not alter or diminish the rate of arterial return required during cardiopulmonary bypass. Based on comparisons to premarket devices, the modified Aegis Catheter is substantially equivalent to the original Aegis Catheter and currently marketed devices.

Product Testing: The determination of substantial equivalence was also based on an assessment of original and modified Aegis devices. Tests for biocompatibility, in vitro and/or in vivo performance were conducted. Results of product testing demonstrated that the Aegis Catheter functions as safely and effectively as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2002

Cardeon Corporation
c/o Ms. Jane Beggs
Vice President, Regulatory Affairs
10161 Bubb Road
Cupertino, CA 95014

Re: K022174
Trade Name: Cardeon® Aegis™ Catheter
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular Catheter, Cannula, or Tubing.
Regulatory Class: Class II (two)
Product Code: DWF
Dated: July 2, 2002
Received: July 3, 2002

Dear Ms. Beggs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

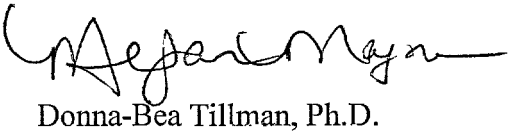
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~K122174~~ K022174

Device Name: Cardeon® Aegis™ Catheter

Indications for Use:

The Cardeon Aegis™ Catheter is intended to perfuse the aorta during open chest procedures on cardiopulmonary bypass up to 6 hours.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use _____

for D. B. Tillman

(Division Sign-Off)
Division of Cardiovascular and Respiratory Devices

510(k) Number K022174